§ 627.57 Ventilated cage areas.

Ventilated cage areas within a room that are solid-walled and bottomed areas for containing multiple cages housing infected animals. The containment for these areas is equivalent to the Class I biological safety cabinet. For testing purposes, they will be treated the same as a Class I biological safety cabinet.

APPENDIX A TO PART 627—REFERENCES

Publications referenced in this part can be obtained from the National Technical Information Services, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

REQUIRED PUBLICATIONS

AR 11–34

Army Respiratory Protection Program. (Cited in §§627.31(h)(2) and 627.31(h)(4).)

AR 40–5

Preventive Medicine. (Cited in §627.8.)

AR 40–10

Health Hazard Assessment Program in Support of the Army Materiel Acquisition Decision Process. (Cited in §627.7(a)(8).)

AR 40–12

Medical and Agricultural Foreign and Domestic Quarantine Regulations for Vessels, Aircraft, and Other Transports of the Armed Forces. (Cited in §627.40(a).)

AR 40–66

Medical Records and Quality Assurance Administration. (Cited in §627.9.)

AR 40–400

Patient Administration. (Cited in §627.8(e).)

AR 70–65

Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities. (Cited in §§627.36(a)(6) and 627.40(b).)

AR 385–10

Army Safety Program. (Cited in §§627.6 and 627.31(h)(4).)

AR 385–69

Biological Defense Safety Program. (Cited in §§627.6, 627.7(a), 627.7(a)(8), 627.7(d), 627.11(c), 627.18(a) and 627.18(f)(1).)

AR 740–32

Responsibilities for Technical Escort of Dangerous Materials. (Cited in §627.39.)

RELATED PUBLICATIONS

A related publication is merely a source of additional information. The user does not have to read it to understand this pamphlet.

AR 40–14

Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials.

ANSI Z86.1–1973

Breathing Air

ASHRAE Standard 62

Bacterial Toxins: A Table of Lethal Amounts, Gill, D.M., Microbiological Reviews, Volume 46, Number 1; March 1982, pages 86–94.

Biohazards Reference Manual

American Industrial Hygiene Association, 1985, Clinical Medicine Branch, Division of Host Factors, Center for Infectious Disease, Centers for Disease Control, Atlanta, GA 30333, telephone: (404) 639–3356, Compressed Gas Association Pamphlet G–7.1

Grade D Breathing Air

Dangerous Goods Regulations, International Air Transport Association (IATA), Publications Section, 2000 Peel Street, Montreal, Quebec, Canada H3A 2R4, Tel (514) 844–6311. DHEW Pub. No. (NIH) 76–1165

Biological Safety Manual for Research Involving Oncogenic Viruses, Executive Order 12196

Safety and Health Programs for Federal Employees, 26 February 1980

Guide for Adult Immunizations, Published by the American College of Physicians, Guide for Transportation of Hazardous Materials, Vol. 4(1) February 10, 1975. (Copies may be obtained from the Office of Research Grants Inquiries, NIH, Department of Health and Human Services, 5333 Westbard Avenue, Bethesda, MD 20205.)

Guidelines for Laboratory Design, Health and Safety Considerations, L. DiBerardinis, et al., John Wiley and Sons, 1987

Guidelines for Prevention of Herpesvirus Simiae (B Virus) Infection in Monkey Handlers, Kaplan, J.E., et al., Mortality and Morbidity Weekly Report, Volume 36, Number 41; October 23, 1987, pages 680–689.

HHS Publication No. (NIH) 88–8395, Biosafety in Microbiological and Biomedical Laboratories

Industrial Ventilation, A Manual of Recommended Practice Published by the American Conference of Governmental Industrial Hygienists.

Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates, The American Journal of Tropical Medicine and Hygiene, 29:1359–1381, 1980.

NIH Guidelines for Research involving Recombinant DNA Molecules (51 FR 16958, May 7, 1986).

NIH publication 86–23, Guide for the Care and Use of Laboratory Animals

NSF Standard #49, National Sanitation Foundation Standard Number 49, Class II (Laminar Flow) Biohazard Cabinetry

Packaging and Shipping of Biological Materials at ATCC, The American Type Culture Collection (ATCC). (Copies may be obtained from the ATCC, 12301 Parklawn Drive, Rockville, MD 20852. Telephone (301) 881–2600.)

Postal Bulletin No. 21246, International Mail-Hazardous Materials

Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards (NCCLS), (H5–A2), Second edition. Vol. 5, No. 1. (Copies may be obtained from the NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085.)

Restricted Articles Tariff 6–D, Air Transport Association

Technical Instructions for the Safe Transport of Dangerous Goods by Air, International Civil Aviation Organization (ICAO) Intereg Group, 5724 Pulaski Road, Chicago, IL 60646, Tel. (312) 478–0900.

The Centers for Disease Control, Office of Biosafety, 1600 Clifton Road NE., Atlanta, Georgia 30333. Telephone (404) 639–3883, or FTS: 236–3883.

9 CFR Parts 102 Through 104, 122

Animals and Animal products.

10 CFR Chapter 1

Nuclear Regulatory Commission.

21 CFR Parts 312, 600 Through 680

Food and drugs.

29 CFR Part 1910

Occupational Health and Safety Administration Safety and Health Standards.

39 CFR Part 111

Postal Service.

40 CFR Parts 1500 Through 1508

Protection of environment.

42 CFR Parts 71 and 72

Public Health Service Foreign Quarantine Regulations.

49 CFR Parts 172 and 173

The Department of Transportation.

Appendix B to Part 627—Resource List for Immunoprophylaxis of Personnel at Risk

B–1. Recommendations for Immunoprophylaxis of Personnel at Risk

Description of disease	Product	Recommended for use in	Source of product
Anthrax	Inactivated vaccine	Personnel working regularly with cultures, diagnostic materials, or infected animals.	USAMRIID.[1]
Botulism	Pentavalent toxoid (A,B,C,D,E) (IND).[2]	Personnel working regularly with cultures or toxin	CDC.[3]
Cholera	Inactivated vaccine	Personnel working regularly with large volumes or high concentrations of infectious materials.	Commercially available.
Diphtheria Tetanus (Adult)	Combined toxoid	All laboratory and animal care personnel irrespective of agents handled	Commercially available.
Eastern equine encephalitis (EEE)	Inactivated vaccine (IND)[2]	Personnel who work directly and regularly with EEE in the laboratory	USAMRIID.[1]
Hepatitis A	Immune Serum Globulin [ISG (Human)].	Animal care personnel working directly with chimpanzees naturally or experimentally infected with Hepatitis A virus.	Commercially available.
Hepatitis B	Serum-derived or recombinant vaccine.	Personnel working regularly with human blood and blood components	Commercially available.
Influenza	Inactivated vaccine	(Vaccines prepared from earlier isolated strains may be of little value in personnel working with recent isolates from humans or animals).	Commercially available.
Japanese Encephalitis	Inactivated vaccine (IND)[2]	Personnel who work directly and regularly with JE virus in the laboratory	CDC.[3]
Measles	Live attenuated virus vaccine	Measles-susceptible personnel working with the agent or potentially infectious clinical materials.	Commercially available.
Meningococcal Meningitis	Purified polysaccharide vaccine	Personnel working regularly with large volumes or high concentrations of infectious materials (does not protect against infection with group B meningococcus).	Commercially available.
Plague	Inactivated vaccine	Personnel working regularly with cultures of *Yersinia pestis* or infected rodents or fleas.	Commercially available.
Poliomyelitis	Inactivated (IPV) and live attenuated (OPV) vaccines.	Polio-susceptible personnel working with the virus or entering laboratories or animal rooms where the virus is in use.	Commercially available.
Pox viruses (Vaccinia, Cowpox, or Monkey Pox viruses).	Live (lyophilized) vaccinia virus	Personnel working with orthopox viruses transmissible to humans, with animals infected with these agents, and persons entering areas where these viruses are in use.	CDC.[3]
Q Fever (Phase II) vaccine	Inactivated (IND)[2]	Personnel who have no demonstrable sensitivity to Q fever antigen and who are at high risk of exposure to infectious materials or animals.	USAMRIID.[1]
Rabies	Human diploid line cell inactivated vaccine.	Personnel working with all strains of rabies virus, with infected animals, or persons entering areas where these activities are conducted.	Commercially available.
Rift Valley Fever	Inactivated virus vaccine (IND)[2]	All laboratory and animal care personnel working with the agent or infected animals and all personnel entering laboratories or animal rooms when the agent is in use.	USAMRIID.[1]
Rubella	Live attenuated virus vaccine	Rubella-susceptible personnel, especially women, working with ''wild'' strains or in areas where these viruses are in use.	Commercially available.
Tuberculosis	Live, attenuated (BCG) bacterial vaccine.	BCG vaccine ordinarily is not used in laboratory personnel in the U.S	Commercially available.
Tularemia	Live attenuated bacterial vaccine (IND).[2]	Personnel working regularly with cultures or infected animals or persons entering areas where the agent of infected animals are in use.	USAMRIID.[1]
Typhoid	Inactivated vaccine	Personnel who have no demonstrated sensitivity to the vaccine and who work regularly with cultures.	Commercially available.
Venezuelan equine (VEE) encephalitis.	Live attenuated (TC83) viral vaccine (IND).[2]	Personnel working with VEE and the Equine Cabassou, Everglades, Mucambo, and Tonate viruses, or who enter areas where these viruses are in use.	USAMRIID.[1]

Western equine encephalitis (WEE)	Inactivated vaccine (IND)[2] with WEE virus.	Personnel who work directly and regularly in the laboratory	USAMRIID.[1]
Yellow Fever	Live attenuated (17D) virus vaccine	Personnel working with virulent and avirulent strains of Yellow Fever virus.	Commercially available.

[1] For information, contact: United States Army Medical Materiel Development Activity, Fort Detrick, Frederick, MD 21701, telephone: (301) 663–7661.
[2] Investigational New Drug (IND).
[3] Clinical Medicine Branch, Division of Host Factors, Center for Infectious Disease, Centers for Disease Control, Atlanta, GA 30333, telephone: (404) 639–3356.
Source: Adapted from recommendations of the PHS Immunization Practices Advisory Committee and Biosafety in Microbiological and Biomedical Laboratories.

APPENDIX C TO PART 627—LABORATORY SAFETY INSPECTION CHECKLIST

C–1. The checklist that follows is not an exhaustive list of the items to consider when inspecting facilities where etiologic agents are used. It does provide some basic guidelines to remind safety and nonsafety professionals of the things that need to be considered in the laboratories they manage. The checklist should be used as follows: All area should be inspected using the general list in C–2. Certain items are optional, such as radiation safety. If no radioactive material is present in the room, then this would not be applicable. For BL–1 facilities the list in C–2 is adequate, while BL–2, BL–3, and BL–4 facilities must use the list in C–2 together with the appropriate list in C–3 to C–5.

C–2. Basic checklist

(a) Housekeeping

(1) Is the room free of clutter?

(2) Are all aisles from the work areas to the available exits maintained clear of obstructions?

(3) Are all safety equipment items unobstructed and ready for use?

(4) Is the room clean?

(b) Fire safety

(1) Is the fire extinguisher hung in its proper place, ready for use, and unobstructed?

(2) Are there excess flammables located outside National Fire Protection Association (NFPA) approved cabinetry?

(3) Are all Class IA flammables that are in breakable containers in pint or smaller containers?

(4) Are all Class IB flammables that are in breakable containers in liter or smaller containers?

(c) Chemical safety

(1) Are the chemicals stored with compatible materials?

(2) Have the chemical fume hoods been certified in the last 6 months?

(3) Are the eyewash and deluge shower unobstructed and ready for use?

(4) Is the eyewash and deluge shower tested regularly to document proper operation?

(5) Is the organic waste container maintained in a closed position?

(6) Are all reagents and solutions properly labeled?

(7) Is a spill kit within a reasonable distance from the work areas?

(8) Is appropriate protective clothing available for the chemical hazards present?

(9) Is there a written hazard communication program?

(10) Have the personnel in the laboratory been trained in the provisions and principles of the hazard communication program?

(11) Are MSDSs located where they are available to the laboratory workers?

(12) Is there a written chemical hygiene plan?

(d) Radiation safety

(1) Are the radioactive materials stored double-contained?

(2) Is the containment for the radiation waste container adequate to preclude the spread of radiation?

(3) Are all containers appropriately labeled with radiation labels?

(4) Are all entrances to the room appropriately labeled?

(e) Electrical safety

(1) Are excess extension cords being utilized?

(2) Are there any frayed cords in the room?

(3) Are there any cords on the floor across normal traffic patterns in the room?

(f) General laboratory safety

(1) Are sharps discarded and destroyed in a safe manner?

(2) Are work surfaces decontaminated daily and after a spill?

(3) Is the appropriate attire worn by everyone in the room?

(4) Is there evidence that personnel eat, drink, smoke, or store food, drinks, or tobacco in the room?

(5) Was mouth pipetting observed?

(6) Are all gas cylinders secured and are all cylinders not in use capped?

(7) Are cylinders of oxidizers stored at least 20 feet from cylinders of flammable gases in the same room?

(8) Are the contents of the cylinders clearly labeled?

(9) Are the cylinders transported on appropriate dollies or hand trucks?

(10) Is there a written respiratory protection program where respirators are used?

(g) Etiologic agents

(1) Are all containers of etiologic agents appropriately labeled?

(i) Are freezers, refrigerators, and similar storage units labeled with the biohazard warning sign?

(ii) Are the storage and shipping containers adequate and properly labeled?

(2) Have all personnel been adequately trained in general microbiological techniques?

(3) Are laboratory doors kept closed when experiments are in progress?

(4) Are all operations conducted over plastic-backed absorbent paper or spill trays?

C–3. Biosafety level 2 supplemental checklist

(a) Are all floor drains filled with water or suitable disinfectant?

(b) Is the SOP for an etiologic agent spill signed by all personnel who work with etiologic agents in the room?

(c) If biological safety cabinets are used, have they been certified within the last year?

(d) Are the appropriate decontaminants available?

(e) Are all entrances to the laboratory posted with—

(1) The appropriate special provisions for entry?

(2) The universal biohazard symbol?

(3) The name and telephone number of the laboratory director or other responsible person?

(f) Is entry limited and restricted?

(g) Are gloves being worn when handling infected animals or infectious or toxic materials?

(h) Is eye and respiratory protection being worn in rooms where nonhuman primates are present?

(i) If materials are being transported offsite for decontamination, is the containment adequate?

C–4. Biosafety level 3 supplemental checklist

(a) Is laboratory clothing decontaminated before being sent to the laundry?

(b) Are all windows and penetrations through the walls and ceilings sealed?

(c) If biological safety cabinets are used, have they been certified within the last year?

(d) Are the appropriate decontaminants available?

(e) Are all entrances to the facility posted with—

(1) The appropriate special provisions for entry?

(2) The universal biohazard symbol?

(3) The name and telephone number of the laboratory director or other responsible person?

(f) Is entry limited and restricted?

(g) Are gloves being worn when handling infected animals or infectious or toxic materials?

(h) Is eye and respiratory protection being worn in rooms where nonhuman primates are present?

(i) Do the monitors indicate that the room is under negative pressure relative to all entrances?

(j) Are all vacuum lines protected with HEPA filters and liquid disinfectant traps?

(k) Is the autoclave being properly maintained and certified?

(l) Is the foot, elbow, or automatic handwash sink operating properly?

(m) Are all operations with etiologic agents being conducted inside biological safety cabinets or other approved engineering controls?

(n) Are all infected animals housed using appropriate primary containment systems?

(o) Do all personnel who enter rooms housing infected animals wear appropriate respiratory protection?

(p) Do personnel who exit rooms having infected animals leave their protective clothing in the animal and laboratory rooms?

(q) If available, has the UV pass box ouput been certified within the last 3 months?

C–5. Biosafety level 4 supplemental inspection checklist

(a) Precautions for all areas.

(1) Are all penetrations through the walls and ceilings sealed?

(2) Are the appropriate decontaminants available and used properly?

(3) Are all entrances to the facility posted with—

(i) The appropriate special provisions for entry?

(ii) The universal biohazard symbol?

(iii) The name and telephone number of the laboratory director or other responsible person?

(4) Is access to the laboratory controlled strictly and documented?

(5) Do the monitors indicate that the room is under negative pressure relative to all entrances?

(6) Are all vacuum lines protected with HEPA filters and liquid disinfectant traps?

(7) Is the autoclave being properly maintained and certified?

(8) Is the foot, elbow, or automatic handwash sink operating properly?

(9) Do the self-closing doors to the facility operate properly?

(10) Do personnel completely exchange street clothing for laboratory clothing before entry and shower upon exiting?

(11) Is the dunk tank disinfectant fresh and appropriate for the agents in use?

(b) Suit areas.

(1) Are all operations with etiologic agents conducted in Class I or II biological safety cabinets?

(2) Do the procedures in place ensure that, as much as possible, the contamination remains inside the cabinets (such as ensuring that everything removed from within the cabinets, such as gloves being worn, instruments, glassware, or similar items, are decontaminated or properly packaged first)?

(3) Are the Class I or II cabinets in the facility certified every 6 months?

(4) Does the suit decontamination shower have adequate appropriate decontaminant available?

(5) Has the suit decontamination shower been used or tested in the last month?

(6) Is the ventilated suit air supply and emergency air supply adequate and working properly?

(7) Is the emergency alarm system working properly?

(8) Are all of the one-piece positive pressure suits available for use in serviceable condition?

(9) Are infected animals housed in appropriate primary containment systems?

(10) Is the static pressure in the suit area negative to all surrounding areas?

(c) Nonsuit areas.

(1) Are all operations with etiologic agents conducted inside Class III biological safety cabinets?

(2) Were the Class III biological safety cabinets certified before initiating the current operation?

(3) Are all infected animals housed in Class III cabinet containment caging systems?

APPENDIX D TO PART 627—PACKAGING AND LABELING REQUIREMENTS FOR SHIPMENT OF ETIOLOGIC AGENTS

D–1. Packaging and Labeling of Etiologic Agents, from HHS publication No. (NIH) 88–8395.

D–2. Guidelines for the Air Shipment of Diagnostic Specimens, from the Air Transport Association of America, Cargo Services Division, 1709 New York Ave., NW., Washington, DC 20006.

APPENDIX E TO PART 627—PERMITS FOR IMPORTATION AND SHIPMENT OF ETIOLOGIC AGENTS

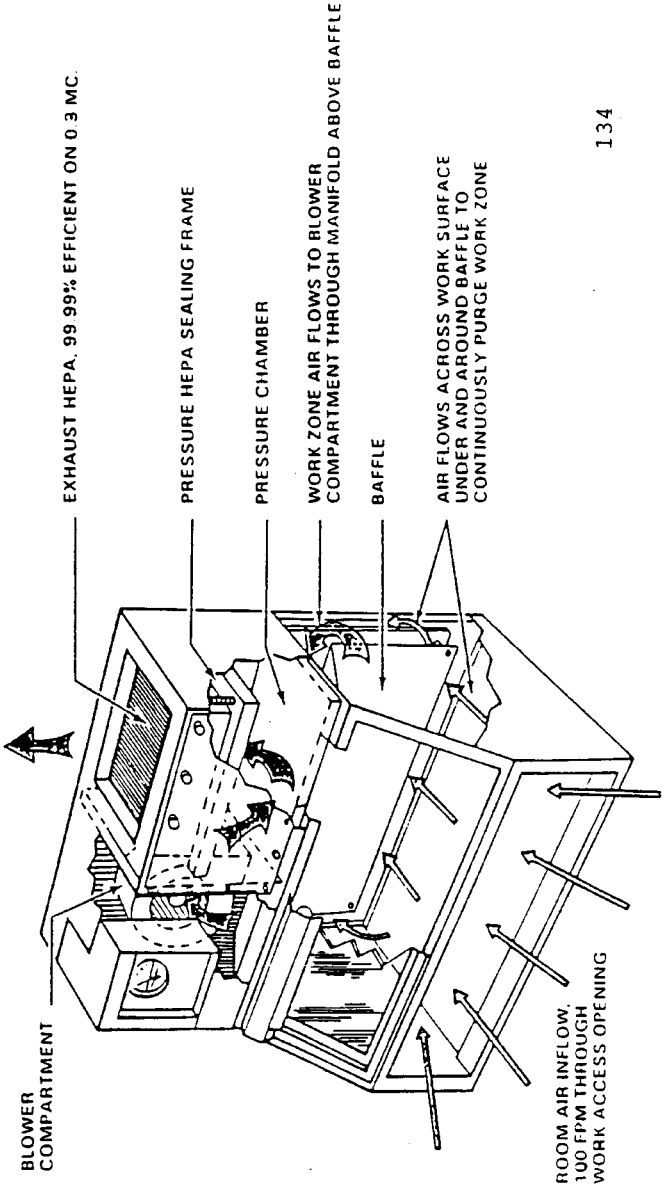
E–1. Permit Application to Import or Transport Agents or Vectors of Human Disease. Department of Health, Education and Welfare, PHS, CDC, Office of Biosafety, Atlanta, Georgia 30333.

E–2. Permit Application to Import Controlled Material; Import or Transport Organisms or Vectors. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Federal Building, Hyattsville, Maryland 20782.

Appendix F to Part 627—Drawings, Biological Safety Cabinets

FIGURE H-1

CLASS I BIOLOGICAL SAFETY CABINET



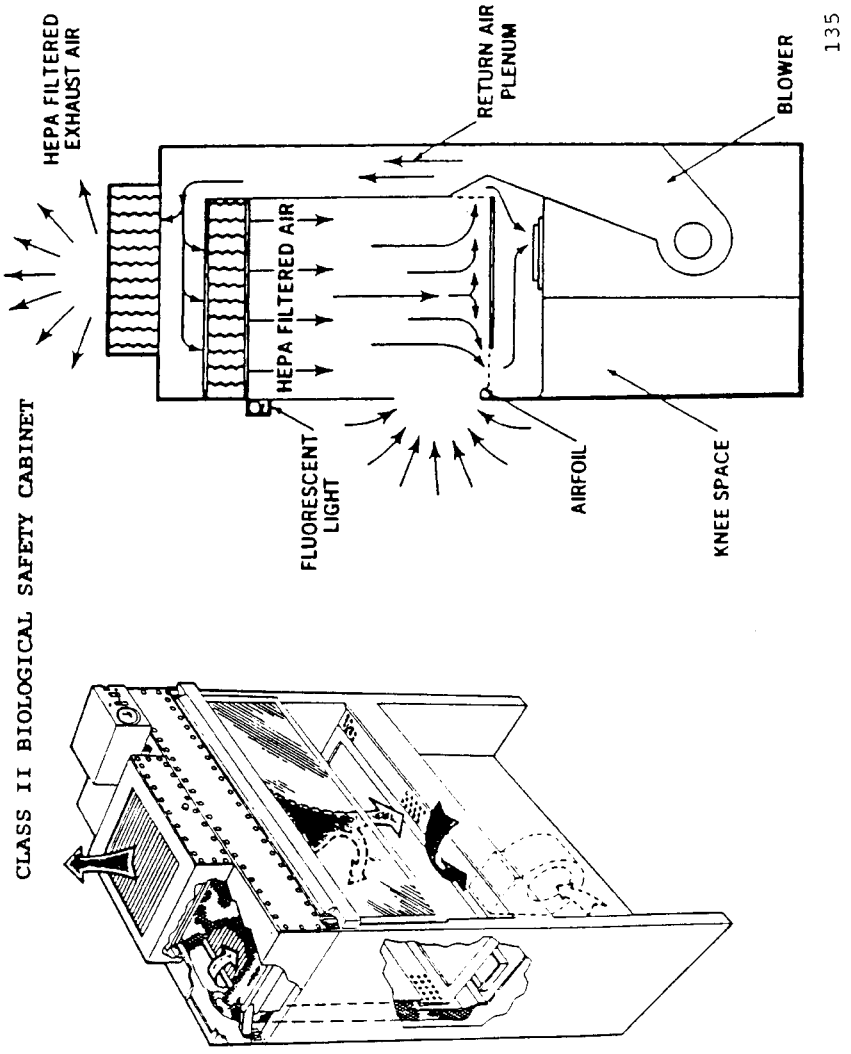


FIGURE H-2

CLASS II BIOLOGICAL SAFETY CABINET

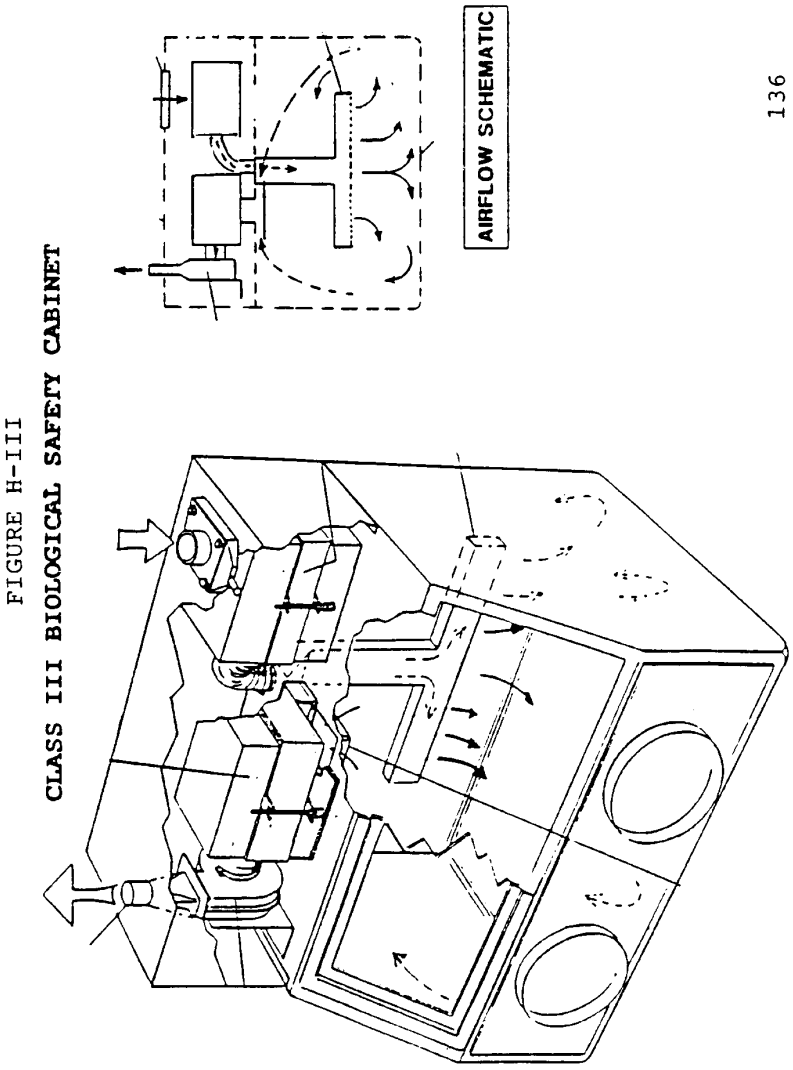


FIGURE H-III
CLASS III BIOLOGICAL SAFETY CABINET

APPENDIX G TO PART 627—GLOSSARY

Abbreviations
AIHA
American Industrial Hygiene Association
AMC
United States Army Materiel Command
ANSI
American National Standards Institute
AR
Army Regulation
ATCC
American Type Culture Collection
ASHRAE
American Society of Heating, Refrigerating, and Air Condition
Engineers, Inc.
BDP
Biological Defense Program
BL
biosafety level
CDC
Centers for Disease Control

CFR
Code of Federal Regulations
DA PAM
Department of Army Pamphlet
DHEW
Department of Health, Education, and Welfare
DOD
Department of Defense
DOT
Department of Transportation
DNA
deoxyribonucleic acid
EPA
Environmental Protection Agency
EtO
ethylene oxide
FDA
Food and Drug Administration
fpm
feet per minute
HEPA
high efficiency particulate air
HHS
Health and Human Services
IATA
International Air Transport Association
IBC
Institutional Biosafety Committee
ICAO
International Civil Aviation Organization
lfpm
linear feet per minute
LS
large-scale
m
meter
min
minute
MSDS
Material Safety Data Sheets
MSHA
Mine Safety and Health Administration
NCCLS
National Committee for Clinical Laboratory Standards
NCI
National Cancer Institute
NEPA
National Environmental Policy Act
NFPA
National Fire Protection Association
NIH
National Institutes of Health
NIOSH
National Institute for Occupational Safety and Health
NRC
Nuclear Regulatory Commission
NSF
National Sanitation Foundation
OSHA
Occupational Safety and Health Administration
pH
the negative logarithm of hydrogen ion concentration
PHS
Public Health Service
PPE
personal protective equipment
ppm
parts per million
psi
pounds per square inch
RCRA–Listed
Resource Conservation Recovery Act of 1976 Listed Hazardous Waste
RDTE
research, development, test, and evaluation
RPO
Radiation Protection Officer
SALS
Subcommittee on Arbovirus Laboratory Safety
SAR
supplied-air respirator
SCBA
self-contained breathing apparatus
SOP
Standing Operating Procedure
TD
to deliver
TLV
threshold limit value
USDA
United States Department of Agriculture
UV
ultraviolet

TERMS

Approved respiratory protection

Equipment which is tested and listed as satisfactory according to standards established by a competent authority (such as NIOSH, Mine Safety and Health Administration (MSHA), or host country agency) to provide respiratory protection against the particular hazard for which it is designed. For military agent protection, DA and Department of Defense (DOD) are the approval authorities. (Approval authority may be specified by law.)

BIOCONTAINMENT AREA

An area which meets the requirements for a BL–3 or BL–4 facility.
The area may be an entire building or a single room within a building. See subpart G for details.

BIOLOGICAL SAFETY CABINETS

Engineering controls designed to enable laboratory workers to handle infectious etiologic agents and to provide primary containment of any resultant aerosol. There are three major classes of cabinets (I, II, and III) and several subclasses of class II cabinets. Each type of cabinet provides a different degree of protection to personnel and to the products handled inside them. The various classes of cabinets are described in detail in subpart H.

BIOSAFETY LEVEL 1

The facilities, equipment, and procedures suitable for work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment.

BIOSAFETY LEVEL 2

The facilities, equipment, and procedures applicable to clinical, diagnostic, or teaching laboratories, and suitable for work involving indigenous agents of moderate potential hazard to personnel and the environment. It differs from BL–1 in that (1) laboratory personnel have specific training in handling pathogenic agents, (2) the laboratory is directed by scientists with experience in the handling of specific agents, (3) access to the laboratory is limited when work is being conducted, and (4) certain procedures in which infectious aerosols could be created are conducted in biological safety cabinets or other physical containment equipment.

BIOSAFETY LEVEL 3

The facilities, equipment, and procedures applicable to clinical, diagnostic, research, or production facilities in which work is performed with indigenous or exotic agents where potential exists for infection by aerosol, and the disease may have serious or lethal consequences. It differs from BL–2 in that (1) more extensive training in handling pathogenic and potentially lethal agents is necessary for laboratory personnel; (2) all procedures involving the manipulation of infectious material are conducted within biological safety cabinets, other physical containment devices, or by personnel wearing appropriate personal protective clothing and devices; (3) the laboratory has special engineering and design features, including access zones, sealed penetrations, and directional airflow; and (4) any modification of BL–3 recommendations must be made only by the commander.

BIOSAFETY LEVEL 4

The facilities, equipment, and procedures required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. It differs from BL–3 in that (1) members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents; (2) laboratory personnel understand the primary and secondary containment functions of the standard and special practices, containment equipment, and laboratory design characteristics; (3) access to the laboratory is strictly controlled by the institute director; (4) the facility is either in a separate building or in a controlled area within a building, completely isolated from all other areas of the building; (5) a specific facility operations manual is prepared or adopted; (6) within work areas of the facility, all activities are confined to Class III biological safety cabinets or Class I or Class II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life support system; and (7) the maximum containment laboratory has special engineering and design features to prevent microorganisms from being disseminated to the environment.

BUILDING

A structure that contains the requisite components necessary to support a facility that is designed according to the required biosafety level. The building can contain one or more facilities conforming to one or more biosafety level.

CONFIRMED EXPOSURE

Any mishap with a BDP agent in which there was direct evidence of an actual exposure such as a measurable rise in antibody titer to the agent or a confirmed diagnosis of intoxication or disease.

ETIOLOGIC AGENTS

Any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 72.3 of the Department of Health and Human Services regulations, and any agent of biological origin that poses a degree of hazard similar to those agents.

FACILITY

An area within a building that provides appropriate protective barriers for persons working in the facility and the environment external to the facility, and outside of the building.

HEPA FILTER

A filter which removes particulate matter down to submicron sized particles from the air passed through it with a minimum efficiency of 99.97 percent. While the filters remove particulate matter with great efficiency, vapors and gases (for example, from volatile chemicals) are passed through without restriction. HEPA filters are used as the primary means of removing infectious agents from air exhausted from engineering controls and facilities.

HUMAN LETHAL DOSE

The estimated quantity of a toxin that is a minimum lethal dose for a 70 kilogram individual based upon published data or upon estimates extrapolated from animal toxicity data.

COMMANDER OR INSTITUTE DIRECTOR

The commander or institute director of an Army activity conducting RDTE with BDP

etiologic agents, or the equivalent, at a research organization under contract to the BDP.

INSTITUTION

An organization such as an Army RDTE activity (institute, agency, center, and so forth) or a contract organization such as a school of medicine, or research institute that conducts RDTE with BDP etiologic agents.

LABORATORY

An individual room or rooms within a facility that provide space in which work with etiologic agents can be performed. It contains all of the appropriate engineering features and equipment required at a given biosafety level to protect personnel working in it and the environment external to the facility.

LARGE-SCALE OPERATIONS

Research or production involving viable etiologic agents in quantities greater than 10 liters of culture.

MAXIMUM CONTAINMENT AREA

An area which meets the requirements for a BL–4 facility. The area may be an entire building or a single room within the building. See chapter 7 for details.

MOLDED MASKS

Formed masks that fit snugly around the mouth and nose and are designed to protect against a nontoxic nuisance level of dusts and powders. These do not require approval by NIOSH or MSHA. Masks made of gauze do not qualify.

POTENTIAL ACCIDENTAL EXPOSURE

Any accident in which there was reason to believe that anyone working with a BDP agent may have been exposed to that agent, yet no measurable rise in antibody titer or diagnosis of intoxication or disease was made. However, the high probability existed for introduction of an agent through mucous membranes, respiratory tract, broken skin, or the circulatory system as a direct result of the accident, injury, or incident.

RESOURCE CONSERVATION RECOVERY ACT OF 1976 LISTED HAZARDOUS WASTE

The waste materials listed by the Environmental Protection Agency under authority of the RCRA for which the agency regulates disposal. A description and listing of these wastes is located in 40 CFR part 261.

SUITE

An area consisting of more than one room, designed to be a functional unit in which entire operations can be facilitated. Suites may contain a combination of laboratories or animal holding rooms and associated support areas within a facility that are designed to conform to a particular biosafety level. There may be one or more suites within a facility.

TOXIN

Toxic material of etiologic origin that has been isolated from the parent organism.[1]

[1] The publication ''Bacterial Toxins: a Table of Lethal Amounts,'' (Gill, D.M. (1982) Microbiological Reviews, *46*:86–94) contains a useful table of mammalian toxicities of numerous toxins.